Docket No.: HO-P00965US0
(PATENT)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
James M. Musser, et al.

Application No.: 08/160,965

Filed: December 2, 1993

Art Unit: 1645

For: VACCINES CONTAINING CYSTEINE PROTEASE AND METHODS TO PROTECT AGAINST GROUP A STREPTOCOCCI

Examiner: J. Hines

TRANSMITTAL OF APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed please find three (3) originals of the APPEAL BRIEF in this Application. The Notice of Appeal was filed on July 23, 2003.

Pursuant to 37 C.F.R. § 1.17(f), the fee for filing the APPEAL BRIEF is $160.00. The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to our Deposit Account No. 06-2375, under Order No. HO-P00965US0 from which the undersigned is authorized to draw.

Dated: September 23, 2003

Respectfully submitted,

By Melissa L. Sistrunk

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APPELLANT'S BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This brief is in furtherance of the Notice of Appeal filed in this case on July 23, 2003.

The fees required under § 1.17(f) for filing this brief and fees therefor are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

In accordance with 37 C.F.R. § 1.192(a), this brief is submitted in triplicate.

This brief contains items under the following headings as required by 37 C.F.R. § 1.192 and M.P.E.P. § 1206:

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is the assignee of all right, title and interest, Baylor College of Medicine, and the licensee, Wyeth. The Assignment was recorded in the records of the U.S. Patent Office on January 31, 1994 on Reel 6852, Frame 0181.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There were 17 claims originally filed in the application. New claims 18-19 were added on March 15, 2001. New claims 20-47 were added on October 29, 2001.

B. Current Status of Claims

1. Claims canceled: 2, 3, and 36-45

2. Claims withdrawn from consideration but not canceled: None

3. Claims pending: 1, 4-35, 46 and 47

4. Claims allowed: None

5. Claims rejected: 1, 4-35, 46 and 47

C. Claims On Appeal

The claims on appeal are claims 1, 4-35, 46 and 47 and are shown in Appendix A.

IV. STATUS OF AMENDMENTS

Appellant filed an Amendment After Final Rejection on May 9, 2003. The Examiner responded to the Amendment After Final Rejection in an Advisory Action mailed June 19, 2003. In the Advisory Action, the Examiner indicated that Appellant's proposed amendments to claims 1, 6, 20, 46, and 47 would be entered.

Accordingly, the claims enclosed herein as Appendix A incorporate the amendments to claims 1, 6, 20, 46, and 47 as indicated in the paper filed.

V. SUMMARY OF INVENTION

The present invention regards methods and compositions related to purified (Page 19, Line 24-Page 20, Line 1) non-proteolytic streptococcal pyrogenic exotoxin B (SPEB) (Page 7, Lines 1-8) that produces an immune response in a mammal against Group A streptococcal infection (Page 7, Lines 1-8), particularly wherein the exotoxin comprises particular amino acid substitutions including Lysine145 (Lys145), Glutamine185 (Gln185), Cysteine192 (Cys192), Histidine340 (His340), Asparagine356 (Asn356) or Tryptophan357 (Trp357) (Page 32, Line 18-Page 33, Line 1).

The Group A streptococcal infection may be selected from the group consisting of pharyngitis, tonsillitis, skin infections, acute rheumatic fever, scarlet fever, post-streptococcal glomerulonephritis, and toxic-shock-like syndrome (Page 7, Lines 10-14). The method may further comprise administering to the mammal a streptococcal M protein antigen (Page 7, lines 15-18).

The composition may be administered parenterally (Page 8, Line 2), such as by subcutaneous and intramuscular administration (Page 8, Lines 2-4). The composition may be administered orally (Page 8, Line 4). The composition may be administered in multiple doses (Page 8, Lines 7-8). The composition may be administered to a human (Page 8, Lines 9-12).

VI. ISSUES

35 U.S.C. §112, paragraph 1

Are claims 1, 4-35, 46 and 47 described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention?

VII. GROUPING OF CLAIMS

The claims stand or fall together.

VIII. ARGUMENTS

The U.S. Patent Office rejects claims 1, 4-35, and 45-47 under 35 U.S.C. §112, paragraph 1, because the Office failed to appreciate that the scope of the claims in this case was adequately described.

Appellant would like to note that although the terms "cysteine protease" and "streptococcal pyrogenic exotoxin B (protein SPEB, or gene *speB*)" are interchangeable to those of skill in the art, Appellant amended the language of the claims to clarify any ambiguities. Claims 1 and 6 are now drawn to immunological compositions containing a purified non-proteolytic streptococcal pyrogenic exotoxin B in lieu of a purified non-proteolytic cysteine protease. For discussion purposes only Appellants refer herein to the sequence as SPEB or *speB*.

The Office asserts that the instant specification fails to provide the identity of the entire *speB* sequence. This statement clearly demonstrates that the Office failed to understand the invention, given that the invention regards an immunological composition and methods utilizing same wherein the SPEB has at least one specific amino acid substitution in its sequence. It presumes that the full sequence from which specific amino acid substitutions are drawn is required for the written description to be commensurate in scope with the claims drawn to specific amino acid substitutions. The Office also asserts that failing to provide a precise description of the *speB* sequence would not allow a person skilled in the art to recognize that the inventor invented what is claimed. Again, the Office fails to recognize that the invention is not the SPEB sequence itself but substitutions at specific locations within this **known and old** sequence.

The Wild-type speB Sequence was Known in the Art Prior to Filing

The position of the Office fails to consider the knowledge of the skilled artisan for this particular art. Upon reading the instant specification, a skilled artisan would recognize that the inventors had possession of the invention at the time of filing because the native *speB* sequence was in the public domain prior to filing. The specification provided sufficient knowledge to the skilled artisan (Page 22, Line 4-Page 23, Line 2) to obviate the need for disclosure of the readily available **known and old** *speB* sequence. The inventors' own article "A conserved *Streptococcus pyogenes* extracellular cysteine protease cleaves human fibronectin and degrades vitronectin" by Kapur et al., *Microbial Pathogenesis* **Nov. 1993**; 15:

327-346, reported the methodical and prolific sequencing of 39 SPEB alleles in 67 *S. pyogenes* strains and explicitly state that 33 of the 39 identified alleles differ in sequence from one another at only one or two amino acids that are clustered in a ten-amino acid region (amino acid positions 308-317). The nucleotide sequences that code for allelic variations within the identified ten-amino acid region are disclosed on page 331 (Figure 3) of the cited volume of *Microbial Pathogenesis*. Furthermore, the figure legend for Figure 3 of the above-cited publication divulges the GenBank accession numbers assigned to the DNA sequences coding for the complete amino acid sequences of the SPEB protein and the 33 highly conserved allelic variants thereof (EMBL/GenBank/DDBL accession numbers L26125-L26162). The GenBank database at the National Center for Biotechnology Information website is a well-known publicly available repository of both DNA and protein sequence information. The GenBank database is utilized consistently by those of skill in this art, and it is well-settled case law that what is conventional or well known to a skilled artisan need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.

Therefore, the complete polynucleotide and amino acids structure of the SPEB protein used as a reference sequence to generate the invention of the instant claims was available to skilled artisans at the time of the instant application and ***is not required, given that the sequence was in the public domain prior to the time of filing***.

Description in the Specification of Knowledge in the Prior Art is Not Required

Appellant is not required to repeat the known sequence in the specification, particularly when it is readily available to the skilled artisan prior to filing. *In re Chilowski*, 108 USPQ 321, 324 (CCPA 1956) ("It is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art. As was said in *Webster Loom Co. v. Higgins et al.*, 105 US 580, 586, the applicant 'may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings.'")

Furthermore, it is also well-settled case law that in claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify

many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Regents of the University of California v. Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. The description need only describe in detail that which is new or not conventional (see *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp. v. General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805), and this is equally true whether the claimed invention is directed to a product or a process. In this case, the chemical material, being DNA and/or its encoded protein, was described in an adequate description of the claimed genus, a non-proteolytic SPEB that provokes an immune response (Page 7, Lines 4-5), and the new details directed to the six specific mutations that impart the non-proteolytic characteristic are provided at Page 32, Line 18-Page 33, Line 1.

Moreover, although *Eli Lilly* (119 F.3 at 1568, 43 USPQ2d at 1406) provides that a definition by function alone does not suffice because it is an indication of what the gene does, rather than what it is, Appellant asserts that structure for the *speB* was provided in the specification. For example, on Page 19, Line 21, Appellant provides a sequence of QPVVKSLLDSK, corresponding to amino acids 146-156 as a structure common to *speB* and its variants. Also, Fig. 8 provides a schematic as to the overall structure of the encoded SPEB protein. Thus, description of structural features of the composition were provided at the time of filing, and Appellant's invention therefore meets the standards set under *Eli Lilly*.

Furthermore, as noted in MPEP §2163, antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. See *Lockwood v. American Airlines, Inc.*, 107 F.3d at 1572, 41 USPQ2d at 1966. Applicants teach antibodies raised against both unsubstituted SPEB and the SPEB variants (Page 35, Lines 3-14).

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption (*In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Given that the Examiner has the burden of presenting a **preponderance** of evidence why a skilled artisan would not recognize Appellant's disclosure as satisfactorily described (*In re Wertheim*, 541 F.2d at 263, 191 UASPQ at 97) (emphasis added), Appellant asserts that the disclosure as provided upon filing was more than adequate and the Examiner errs in the allegation of lack of written description.

Purification Scheme was Provided in the Specification

Appellant clearly had possession of the invention at the time of filing despite not providing the already publicly available *speB* sequence. The instant specification details the purification scheme used by the Appellant to purify *S. pyogenes* cysteine protease and *in vitro* and *in vivo* biochemical, functional and immunologic evidence to confirm that the material obtained from the disclosed purification scheme is the purified cysteine protease whose derivatives are used in an immunologic composition of current claim 1.

The biochemical, functional and immunological examples cited in the instant specification on page 19 and Fig. 1; page 21 and Fig. 3; and page 6 lines 19-28 and Fig. 10 are drawn from the instant specification and are also disclosed in Kapur et al., *Microb Path*, Nov. 1993 and Kapur et al., *Proc. Natl. Acad. Sci.* 90: 7676-7680 (Aug. 1993). They are sufficient for one of ordinary skill in the art to recognize that the inventors were in possession of SPEB from *S. pyogenes* that can be used in an immunological composition. Furthermore, a skilled artisan would undoubtedly recognize that Appellant was able to purify the exemplary SPEB variants of current claim 1 that contain one or more amino acid substitutions specifically engineered to disrupt enzymatic activity or alter immunogenicity.

The Specification Discloses Identifying Characteristics of the Sequence

The disclosure, as instantly filed, follows C(2) written description criteria set out in Chisum § 7.04[1][c] 7-176 ¶5 as follows: "If the complete structure is not disclosed, determine whether the specification discloses other relevant identifying characteristics, *i.e.* physical and/or chemical characteristics and/or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to describe the claimed invention in such full, clear concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Disclosure of any combination of such identifying characteristics that would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. In such a case, a rejection for lack of written description under 35 U.S.C. §112 ¶ 1 must not be made".

Appellant asserts that the specification provides identifying characteristics in keeping with Chisum § 7.04[1][c] 7-176 ¶5 to demonstrate that they had possession of the claimed species. For example, on page 7, line 7, Appellants identified that the composition is preferably a translated portion of the *speB* gene and also comprises at least one mutation at

Lysine145 (Lys145), Glutamine185 (Gln185), Cysteine192 (Cys192), Histidine340 (His340), Asparagine356 (Asn356) and/or Tryptophan357 (Trp357) (Page 32, Lines 18-Page 33, Line 1). These elements are limitations to Appellant's broadest claims. Furthermore, Appellant identified that the composition must provoke an immune response (Page 7, Lines 1-8). In specific embodiments, the SPEB must be purified (Page 19, Line 24-Page 20, Line 1) and be non-proteolytic in function (Page 7, Lines 1-8). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or ***by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.*** See, *e.g. Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S. Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical,* 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (emphasis added).

Appellant asserts distinguishing identifying characteristics were provided to show that possession of the claimed invention was in hand at the time of filing. As stated above, although *Eli Lilly* (119 F.3 at 1568, 43 USPQ2d at 1406) sets forth that a definition by function alone does not suffice because it is an indication of what the gene does, rather than what it is, Appellant provides structural characteristics for the *speB* in the specification, particularly a sequence of QPVVKSLLDSK, corresponding to amino acids 146-156 as a structure common to SPEB and its variants (Page 19, Line 21), and a schematic as to the overall structure of the encoded SPEB protein (Fig. 8). Therefore, description of structural features of the composition were provided at the time of filing, and Appellant's invention meets the standards set under *Eli Lilly*.

The Disclosure Teaches the Invention of Mutated SPEB Residues

Appellant respectfully asserts that the Examiner misunderstands the nature of the invention and therefore erroneously interprets the specification. The pending claims are directed to a composition and its utilization in a method, wherein the composition is a SPEB having at least one amino acid substitution narrowly selected from six very specific substitutions. The invention is not the reference SPEB sequence itself, for that was known in the art at the time of filing. Instead, the invention is at least one modification of the known

SPEB sequence by providing specific amino acid substitutions in it.

The specification teaches generation of mutant speB proteins (Example 20 at Page 32, Line 3-Page 35, Line 1). Particularly, Example 20 delineates obtaining the speB gene (Page 33, Lines 13-15), the details of which are taught on Page 22, Line 4-Page 23, Line 4. This is followed by oligonucleotide-directed mutations based on an old and well-known method in the art (Page 33, Line 25-Page 34, Line 4 and Figure 9).

Thus, Appellant's specification itself, directed toward substitutions in SPEB, is clearly written and described therein to allow a skilled artisan to recognize that there was possession of the invention at the time of filing.

The Specification Provides Evidence that Appellant Had Possession

The Examiner alleges that one skilled in the art would not have viewed the teachings of the specification sufficient to show that Appellent was in possession of an immunogenic composition comprising the mutated SPEB and method of producing an immune response, as asserted in the specification as instantly claimed. This is clearly in error, given that the specification provides description of experiments that utilized the *speB* sequence. That is, a detailed description of the method used by the inventors to amplify the *speB* gene and its flanking regions from *S. pyogenes* chromosomal DNA using a polymerase chain reaction (PCR) strategy is disclosed on pages 22 and 23 of the instant specification. The specific primer sequences used to amplify the *speB* gene are disclosed on page 55, lines 15 and 16 of the instant specification. Additionally, page 22, lines 18-21 discloses the sequences of internal primers used by the inventors to sequence the complete *speB* gene. PCR and DNA sequencing were highly developed arts at the time of the instant application and the written description would allow a person of ordinary skill in art to recognize that **the inventors had knowledge of the DNA sequence** of the *speB* gene that was used to perform the PCR experiments. The entire coding region of the *speB* gene (which directs production of the entire speB protein) was amplified by PCR with synthetic primers specific for only that sequence (Page 22, Line 4-Page 23, Line 4). ***This PCR was clearly not performed without knowledge of the DNA sequence.*** Furthermore, this passage informed the skilled artisan what the sequences of *speB*-specific PCR primers were to be able to amplify the sequence themselves.

Site-directed mutagenesis and random mutagenesis protocols disclosed in the instant

specification also illustrate possession of the invention, particularly of the speB sequence. Site-directed mutagenesis was a well-developed art at the time the application was filed, and Appellant asserts that the instant specification adequately conveys to a person of ordinary skill in the art that the inventors had knowledge of the *speB* DNA and amino acid sequences. Appellant also asserts that methods and procedures described in the instant specification allows the inventors and one of skill in the art to mutate amino acids 145, 185, 192, 340, 356 and 357, such as into alanines. Again, ***the site-directed mutagenesis described in the specification clearly illustrates that the inventors knew the identity of the sequence being mutated***, so this description verifies that the inventors had possession of the sequence at the time of filing.

Furthermore, both site-directed and random mutagenesis techniques are described in the application. Figure 8 describes the specific amino acid substitutions at positions 145, 185, 192, 340, 356, and 357, referred to in the specification on page 32, line 20. On page 32, line 16, the rationale and mutagenesis scheme is described in such a way as to create mutants which "(i) disrupt protease activity; (ii) prevent zymogen processing; (iii) prevent substrate binding; and (iv) alter immunoreactivity."

Well-known case law supports Appellant's position. *Emory University v. Glaxo Wellcome, Inc.*, 44 USPQ 2d 1407 states that "to meet the requirement of §112, the patent application need not utilize any particular form of disclosure. Instead 'the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed'". *In re Alton*, 76 F.3d 1168, 1172 states that "The adequate written description requirement, ...serves 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material'".

Furthermore, because the general methods of immunizing against streptococcal infection were known in the prior art, it is as though they were written out in the patent application. Appellant is not required to repeat the sequence in the specification, particularly when it is readily available to the skilled artisan. *In re Chilowski*, 108 USPQ 321, 324 (CCPA 1956) ("It is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art. As was said in *Webster Loom Co. v. Higgins et al.*, 105 US 580, 586, the applicant

'may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings.'") The teachings in Appellant's specification, coupled with the knowledge that one of skill in the art would glean from the prior art, would allow one to use the streptococcal *speB* as an immunological composition in humans.

A Skilled Artisan Would Know the Significance of the Particular Substitutions

Appellant asserts that the application on pages 32, line 16 to page 35, line 1, describes the method for the creation of the genus of mutated *speB* and a rationale for specifically mutating amino acids Lys145, Gln185, Cys192, His340, Asn356 and Trp357 into structurally neutral alanines. The Examiner states in the Advisory Action that without the reference *speB* sequence, one would not know the significance of substituting a particular amino acid in the sequence. Appellant asserts that the numbering system for SPEB protein is consistent with standard methods in the art, and one of skill in the art is aware of the position of the amino acids. Thus, one of skill in the art is capable of determining amino acids at positions 145, 185, *etc.* Appellants reiterate that a skilled artisan in the exemplary case referring to a Lys145 substitution, would recognize that any allele of the *speB* sequence having a lysine at position 145 of the protein sequence would be within the scope of the claim, and one of skill in the art knows how to determine this. For example, a skilled artisan would take one of the GenBank Accession numbers **known in the art at the time of filing**, obtain the *speB* sequence on the world wide web address of the GenBank database, and look at the 145th position of the protein sequence for a lysine (symbolized as K by standard notation in the art).

Thus, there would be clear understanding of the particular amino acids being substituted from the known *speB* sequence.

In Summary

The teachings of the instant specification would allow a skilled artisan to recognize that the inventors were able to purify recombinant wild-type (including known allelic variants) or engineered *speB* from *S. pyogenes* that express a gene encoding a non-proteolytic speB containing mutations at the amino acids Lys145, Gln185, Cys192, His340, Asn356 and Trp357, or genes including two or more mutations at amino acids Lys145, Gln185, Cys192, His340, Asn356 and Trp357 (see at least Page 19, Line 24- Page 20, Line 1). *In re Alton*, 76

F.3d 1168, 1175 states that "If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, **even if every nuance of the claims is not explicitly described in the specification,** then the adequate written description requirement is met" [emphasis added].

The recombinant proteins containing the amino acid substitutions would have then been easily purified using the purification procedure described in the instant specification (Page 19, Line 24-Page 21, Line 1) and incorporated into an immunological composition comprising a physiologically acceptable non-toxic vehicle containing a purified non-proteolytic SPEB having at least one amino acid substitution at Lys145, Gln185, Cys192, His340, Asn356 and/or Trp357, thereby producing an immune response in a mammal against Group A streptococcal infection. Therefore, the Appellant asserts that disclosure of the entire speB sequence is not required in the present specification, given that it was already known at the time of filing, nor is the reference sequence required to show to a person of ordinary skill in the art that the inventors were in possession of the claimed invention at the time of the instant application, given the nature of the experiments described in the application. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996) states that "*ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead the disclosure need only **reasonably** convey to persons skilled in the art that the inventor had possession of the subject matter in question" (emphasis added). The essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the claimed subject matter (see *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977)), and Appellant vehemently asserts that this was achieved.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, applicant was in possession of the claimed invention. *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. Appellant asserts that the specification did provide clear possession of the invention. Appellant reminds the Board that the written description requirement is a question of fact which must be resolved on a case-by-case basis (see, *e.g. Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ 2d at 1116 (Fed. Cir. 1991)), and Appellant asserts that the instant specification certainly met the standards for written description under 35 U.S.C. §112, paragraph 1.

Appellant respectfully requests reversal of the Examiner's rejection and subsequent allowance of all pending claims.

Dated: Sept. 23, 2003

Respectfully submitted,

By _____

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